

**REMARKS**

Claims 11-18 have been examined and rejected, and now remain pending in this application.

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 11-18.

**Rejection of Declaration filed under 37 CFR 1.131**

The declaration filed on October 12, 2004 under 37 CFR 1.131 was found to be ineffective by the Examiner.

In making this rejection, the Examiner alleges that the claimed device comprises three components: (1) a means for collecting reflectance data (2) means for comparing reflectance data and (3) a means for actuating fluid sample movement. The Examiner further alleges that the submitted Invention Disclosure shows only the means for collecting reflectance data and the means for comparing reflectance data but does not disclose the means for actuating fluid sample movement.

According to MPEP 715.07: When reviewing a 37 CFR 1.131 affidavit or declaration, the examiner must consider all of the evidence presented in its entirety, including the affidavits or declarations and all accompanying exhibits, records and "notes." An accompanying exhibit need not support all claimed limitations, provided that any missing limitation is supported by the declaration itself.

As set forth below, the Applicants maintain that the submitted Invention Disclosure is sufficient enough to establish a reduction to practice of the present invention in this country or a NAFTA or WTO member country prior to the effective date of the Shartle reference.

The present invention is directed to a meter that detects the application of a fluid sample onto a test strip. The meter determines the sample application event by comparing the percentage change of the signal with a threshold value. As such, the inventive feature is the accuracy of the reflectance data and its corresponding sample present signal, which in turn, triggers the actuating means to actuate a sample movement means.

The Applicants contend that the novel and inventive components comprise a means for collecting reflectance data and a means for comparing reflectance data as provided in the submitted Invention Disclosure. Furthermore, the actuating means need not be disclosed to be included in the invention because it is an inherent part of the disclosure. Moreover, according to the specification at P.

11, lines 16-20, "The subject devices also generally include a means for actuating a bladder on the device in response to the sample present signal. Any convenient actuation means may be present, so long as it is capable of decompressing the bladder in response to the sample present signal." In addition, P. 2 of the Invention Disclosure provides that "when enough sample condition is met, the assay system triggers the actuator, and draws the sample into the reaction area." It would be clear to one of skill in the art that a sample present signal is the triggering mechanism for the actuating means and as such not an element required to be included in the Invention Disclosure Drawings.

In view of the above remarks, the Applicants contend that the submitted Invention Disclosure is sufficient enough to establish a reduction to practice of the present invention in this country or a NAFTA or WTO member country prior to the effective date of the Shartle reference. Therefore, the Applicants respectfully request that the application pass to issuance.

#### **Rejections Under §103**

Claims 11, 12, and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660. Claims 13 and 15-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '66 in view of U.S. Patent 5,674,699.

In view of the above remarks which clearly demonstrate that the invention was conceived and reduced to practice by the inventors prior to July 20, 1998, the Applicants respectfully request that this rejection be withdrawn.

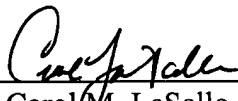
**Conclusion**

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, Order No. LIFE-009.

Respectfully submitted,  
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